

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
_____)	MDL No. 2419
)	Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO:)	
)	
ALL CASES)	

**MEMORANDUM IN SUPPORT OF SAINT THOMAS ENTITIES' MOTION TO
COMPEL INVOKING DEFENDANTS TO PRODUCE CERTAIN DOCUMENTS**

The trial in *U.S. v. Cadden et al.*, No. 1:14-cr-10363 (RGS), was recently set for April 4, 2016.¹ In connection with recent discovery disputes before Judge Boal in that criminal case, the Saint Thomas Entities have learned that numerous, highly relevant documents (including materials seized when NECC was raided) have been provided by the government to the criminal defendants, who have refused to produce them in the MDL civil litigation. The documents at issue are discoverable regardless of how this Court rules on the applicable law to be applied in the Tennessee cases. Because there is no basis for withholding the materials in question, and because the Saint Thomas Entities need this discovery in connection with impending expert disclosure deadlines, this Court should compel production of all such materials other than patient medical records or prescription records.

ARGUMENT AND AUTHORITIES

Federal Rule of Civil Procedure 26(b)(1) provides:

Unless otherwise limited by court order, the scope of discovery is as follows:
Parties may obtain discovery regarding *any nonprivileged matter that is relevant to any party's claim or defense*—including the existence, description, nature,

¹ See *Cadden*, No. 1:14-cr-10363, Dkt. No. 282.

custody, condition, and location of any documents or other tangible things and the identity and location of persons who know of any discoverable matter. For good cause, the court may order discovery of any matter relevant to the subject matter involved in the action. Relevant information need not be admissible at the trial if the discovery appears reasonably calculated to lead to the discovery of admissible evidence. All discovery is subject to the limitations imposed by Rule 26(b)(2)(C).

The United States Supreme Court has further held that the limits set forth in Rule 26 must be “construed broadly to encompass *any matter that bears on, or that reasonably could lead to other matters that could bear on, any issue that is or may be in the case.*”² It is hard to imagine more relevant materials to this civil litigation, spanning hundreds of cases in state and federal courts across the United States, than the materials the government has disclosed in the criminal actions against those who are being prosecuted for causing the contamination that injured the plaintiffs in each of the civil actions.

To put this issue in context, the PSC is claiming that the thousands of health care providers who used NECC should not have done so. The first question that any jury presented with such an argument will want to know is, “how did the contamination occur?” That is the same, central question the government must prove in the criminal case. In order to answer that question, witnesses from NECC will be needed to explain how product was being compounded, the procedures being used, and how those procedures did or did not vary from the written procedures that were supposed to be followed and/or the documentation purportedly reflecting what was done. It is no wonder that the government has gotten immunity orders for certain witnesses to make sure it can get that testimony. The Saint Thomas Entities intend to present the same evidence to establish its defense that the persons who caused or contributed to the contamination are solely responsible for the plaintiffs’ damages. Whether couched as “sole

² *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 351 (1978) (emphasis added).

proximate cause” or “unforseeability” or “no breach,” this evidence is highly relevant regardless of what law is applied or where the case is tried.

Indeed, the Conigliaros, Mr. Cadden, and Mr. Chin have been provided thousands of relevant documents on matters highly relevant to this MDL, including without limitation the following:

- Interview reports and agent notes for 260 witnesses and 4 organizations;³
- Transcripts of depositions of witnesses from Analytical Research Laboratories (“ARL”),⁴ the testing lab that tested the contaminated MPA and deemed it sterile;
- Photos taken during the execution of the first and second search warrants at NECC;⁵
- Additional photos taken from NECC;⁶
- Witness interview reports;⁷
- Glenn Chin’s personal e-mails;⁸
- 26 discs containing audio and video recordings of NECC sales trainings labeled “NECC Sales Audio and Video”;⁹
- 5 discs labeled, in part, “Barry Cadden Sales Education”;¹⁰
- Binder labeled, in part, “necc Training Binder”¹¹

³ See Exhibits to Government’s Opposition to Defendants’ Preliminary Motion to Compel Discovery (attached hereto), Ex. A at 4 (excerpt of Jan. 14, 2015 discovery letter from Government to counsel for Barry Cadden), *U.S. v. Cadden*, Dkt. No. 237-1.

⁴ *Id.* at 2.

⁵ *Id.* at Ex. C, p. 3.

⁶ *Id.* at Ex. A, p. 2.

⁷ *Id.* at Ex. C, p. 3.

⁸ *Id.* at Ex. A, p.4.

⁹ *Id.* at Ex. C, p.3.

¹⁰ *Id.* at Ex. E, p.3.

- Handwritten documents relating to recall and training;¹²
- Binders labeled “Hospital Team Training Binder” and “Surgery Center Training Binder”;¹³
- Employee listing with addresses and phone numbers;¹⁴
- Immunity orders (*i.e.* listing of persons who may be deposed and cannot refuse to testify based on the Fifth Amendment);¹⁵
- Yellow notepad and 2 sheets of yellow paper with notes regarding methylprednisolone acetate;¹⁶
- Documents and records related to NECC and its affiliated organizations;¹⁷
- Documents and records obtained from state and federal regulators;¹⁸
- Preliminary transcripts of selected NECC sales training recordings;¹⁹ and
- Packet labeled, in part, “Do you have questions about specific risk levels for any of your hospital’s compounded preparations?”²⁰

¹¹ *Id.* at p. 4.

¹² *Id.* at p. 6.

¹³ *Id.* at p. 7.

¹⁴ *Id.* at p. 8.

¹⁵ *Id.* at Exhibit A, p. 3. Barry Cadden, Lisa Conigliaro-Cadden, Gregory Conigliaro, Carla Conigliaro, Douglas Conigliaro, Glenn Chin, Ameridose LLC, GDC Properties Management, LLC, Medical Sales Management, Inc., and Steven Higgins have all refused to participate in discovery to some extent because of their own or their affiliated agents’ Fifth Amendment concerns.

¹⁶ *Id.* at Exhibit E, p. 9.

¹⁷ *Id.* at Exhibit A, p. 2.

¹⁸ *Id.*

¹⁹ *Id.* at Ex. C, p. 3.

²⁰ *Id.* at Ex. E, p. 8.

This is but a small sample of important documents in the possession of Mr. Cadden and his cohorts. The government has even provided them with a spreadsheet “identifying the Bates range of e-mails and records from the NECC SW Edata database that *the government has identified during the course of its review as either ‘hot’ or ‘relevant.’*”²¹

The relevancy of the documents in the hands of the Conigliaros, Mr. Cadden, and Mr. Chin cannot be understated.²² For example, as noted above, there have been hundreds of witness interviews which have been produced to them. These witness interviews will provide key insight into who the Saint Thomas Entities should depose and/or call to trial in their cases. They will also provide invaluable evidence for the Saint Thomas Entities’ experts to review and rely upon in connection with providing their reports, which are currently due in November.

Pictures taken by the government when they raided NECC are also discoverable in these civil proceedings. The condition of the facility when it was in operation is relevant to the claims against health care providers, and these pictures may provide insight on that question (or at the very least, combined with the witness lists and statements, will permit the parties to depose the people who can answer such questions).

As a further example of the need for evidence from the criminal proceeding, the Court may recall that prior to settling, Liberty Industries, Inc. moved for summary judgment and attempted to strike the declaration of Dr. Philip J. Austin, who inspected the NECC cleanrooms in December 2012. One of Liberty’s arguments was that Dr. Austin “provides no basis for his

²¹ *Id.* at Exhibit A, p.6 (emphasis added).

²² Nearly all of the documents are responsive to discovery previously sent to the individuals. Out of an abundance of caution given the impending discovery deadline, the Saint Thomas Entities recently served a new request for all documents provided by the government other than patient medical records and prescriptions. A letter requesting these specific documents was sent on May 14, 2015. The Saint Thomas Entities received no response.

conclusions that the MPA was compounded in the 2006 cleanroom built by Liberty” Liberty Industries, Inc.’s Motion to Strike the Amended Declaration of Philip J. Austin, PhD [Dkt. No. 1661] at p. 4. Like the PSC, the Saint Thomas Entities also assert that Liberty’s design and installation defects caused the contamination at issue. Mr. Cadden and Mr. Chin certainly know where the MPA at issue was compounded, and evidence of this fact is likely to be revealed at the criminal trials (whether by the FDA’s investigation and interviews, the government’s grant of immunity to a witness who then testifies as to the location where the MPA was compounded, etc.). Indeed, while the Court denied Liberty’s motion for summary judgment, it noted there were “serious questions as to the ability of plaintiffs to prove causation at trial” Memorandum of Decision [Dkt. No. 1613] at p. 5. The evidence collected by the government on the cause of the contamination – which they too must prove – is highly relevant to the ability of the civil litigants to establish causation as well.

It is clear from the disclosures to date in the criminal proceeding that the same evidence collected by the government and given to the Conigliaros, Mr. Cadden and Mr. Chin is highly relevant to this civil litigation. In fighting for more discovery in the criminal action, these same defendants argued that they “need the tools sought in these preliminary requests to properly navigate these materials *and to have a fair shot at preparing for a lengthy and complicated trial.*” *See U.S. v. Cadden*, Defendants’ Memorandum in Support of Preliminary Motion to Compel Discovery (“Criminal Defendants’ Memo”), Dkt. No. 231 at 25 (emphasis added)). The Saint Thomas Entities deserve the same “fair shot” in their “lengthy and complicated” trials.

There is no Fifth Amendment privilege against producing in civil litigation what the government has provided in a criminal trial. *See eBay, Inc. v. Digital Point Solutions, Inc.*, 2010 U.S. Dist. LEXIS 7997 (N.D. Cal. 2010). In *eBay*, eBay moved to compel production of

documents from a group of relatives and friends who had conducted business under several related entities. *Id.* at *2-*3. Because they were under criminal investigation, they refused to produce documents, even those already in the government’s possession, asserting that the Fifth Amendment protected them from such disclosure. They also claimed the government had seized and yet to return some of the records. *Id.* at * 20. The court compelled production of everything physically possible to produce, explaining:

As to the substance of the motions, the Court concludes that ***Defendants must produce the documents already in the government’s possession*** to the extent that such production is physically possible. While the Fifth Amendment prohibits compelling acts that are testimonial and incriminating . . . , ***Defendants cannot incriminate themselves merely by turning over information already in the hands of the government agents investigating them.*** *Henry v. Sneiders*, 490 F.2d 315 (9th Cir. 1974) (rejecting a claim of Fifth Amendment protection of an indicted defendant’s records because ***even if the records were incriminating, their disclosure in the civil case would not have tended to incriminate the defendant. Any incriminating information was already in the hands of the prosecuting authorities.***). To the extent Defendants believe that selecting the documents corresponding to a given specific discovery request would itself be an act protected by the Fifth Amendment, eBay has indicated that it is willing to accept the documents en masse.

Id. at *21 to *22 (emphasis added).

The Saint Thomas Entities have tried to avoid seeking a stay of civil proceedings despite the fact one is often warranted in light on ongoing related criminal proceedings. *See In re Grand Jury Proceedings (Williams)*, 995 F.2d 1013, 1018 n.11 (11th Cir. 1993) (finding that stays of civil proceedings may “prove useful,” in spite of the delays they cause, “as the criminal process may determine and narrow the remaining civil issues”); *Brock v. Tolkow*, 109 F.R.D. 116, 120 (E.D.N.Y. 1985) (holding that “the resolution of the criminal case might reduce the scope of discovery in the civil case or otherwise simplify the issues”). In this case, the Government, in briefing concerning discovery sought from the FDA by other Tennessee Defendants, has recognized as much. *See* FDA’s Memorandum in Support of FDA’s Motion for Protective Order

(“FDA Memo”) at 14 (citing above cases) [Dkt. No. 1838-1]. But if these civil actions are going to proceed concurrently with the criminal case, the highly relevant evidence must be made available to the Saint Thomas Entities and other civil defendants so they can defend themselves.

WHEREFORE, the Saint Thomas Entities request an order compelling the Conigliaros, Mr. Cadden and Mr. Chin to produce the documents the government has produced to them other than patient medical records and prescription records.

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Dated: July 30, 2015

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CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 30th day of July, 2015.

/s/ Sarah P. Kelly

SARAH P. KELLY

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